

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/576,813

Applicant: Stiefel

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Examiner: Elizabeth A. Gwartney

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Customer No.: 23460

Commissioner for Patents
P.O. Box 1450
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DECLARATION UNDER 37 C.F.R. § 1.132 OF DR. THOMAS STIEFEL

1. I, Dr. Thomas Stiefel, am the inventor of the subject patent application. I currently am Managing Director of Biosyn Arzneimittel GmbH, which is the assignee of the subject patent application. A copy of my *curriculum vitae* is attached hereto as Exhibit 1.

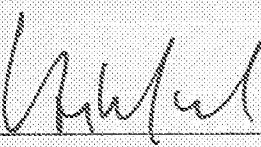
2. In my experience, in intensive care patients, the administration of a composition comprising selenium and zinc in the ranges of 0.5-2 mg and 10-100 mg, respectively, effectively compensates for selenium deficiencies in the patient. In contrast, selenium supplement compositions commercially available at the time the application was filed could not adequately compensate for selenium deficiencies.

3. To my knowledge, the limitations of the selenium supplement compositions commercially available at the time the application was filed were unknown by those in the art. Indeed, these limitations were first recognized through research that was performed at my direction and supervision (see Table 1 of the application).

4. To address these limitations, a composition called Syntrace®, which comprises a daily dose of 1 mg of selenium and a daily dose of 30 mg of zinc was developed under my supervision. This dose of selenium is more than twice the daily dose recommended by the World Health Organization at the time the application was filed (i.e., 400 µg). The administration of the Syntrace® composition produced normal levels of selenium in the blood and serum of patients, without toxic side-effects.

5. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 08/11/2010



Thomas Stiefel